

REMARKS/ARGUMENTS

This case has been carefully reviewed and analyzed in view of the final Office Action dated 6 June 2008. Responsive to the rejections made in the Office Action, Claims 14 and 25 have been amended, and new Claims 36-48 have been added by this Amendment.

In the Office Action, the Examiner rejected Claim 25 pursuant to 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner stated that the limitations of Claim 25 have been added to Claim 14, and therefore, should be cancelled because Claim 25 fails to further limit newly-amended independent Claim 14. Claim 25 has now been amended to further limit newly-amended Claim 14. It is believed that with the cancellation of Claim 25, the Examiner's rejection pursuant to 35 U.S.C. §112, second paragraph, has been obviated.

The Examiner has rejected Claims 14-17, 23, and 25 pursuant to 35 U.S.C. §103(a) as being unpatentable over the Stadler, et al. reference (U.S. Patent No. 6,128,526) (hereinafter "the Stadler reference"). The Examiner next rejected Claims 18, 19, and 22 pursuant to 35 U.S.C. §103(a) as being unpatentable over the Stadler reference. Finally, the Examiner rejected Claims 20, 21, and 24 pursuant to 35 U.S.C. §103(a) as being unpatentable over the Stadler reference.

As newly-amended independent Claim 14 now more clearly recites, Applicants' system further includes among its combination of features an electrical

circuitry means for determining the time of occurrence of a fiducial marker within QRS complex of successive beats within the electrogram. Further, the system includes a processor means for calculating the time period between successive fiducial points, that time, being referred to as an R-R interval. The R-R interval for a specific beat within the electrogram being a difference in time of occurrence of the fiducial point of a first beat to the time of the occurrence of the fiducial point of the preceding beat. The system now includes a telemetry system for receiving sub-segment timing information from an external device, and a random access memory for storing the sub-segment timing information received from the external device such that the processor is configured to determine the start time of the sub-segment based on the values of the calculated R-R interval and the sub-segment timing information. Additionally, the processor is configured to detect the cardiac event by further analysis of the signal amplitude of the at least one sub-segment of the at least one beat of the electrogram. In response to a determination that a cardiac event has occurred, an alarm signal is sent to the alarm device.

New independent Claim 37 is directed to a system for accessing cardiac function based on the electrical signal from a patient's heart as measured by implantable electrodes. The system includes a means for receiving a first plurality of user selected offset times associated with a corresponding plurality of R-R intervals. Further, the system includes an electrical circuitry means for determining the R-R intervals. Further still, the system includes a processor means for determining a first particular offset time relative to a beat fiducial point of one beat of the electrical

signal, wherein the first particular offset time is a function of a R-R interval associated with the one beat such that the first particular time offset is based on at least one of the first plurality of user selected offset times. Finally, the system includes a processing means for assessing cardiac function based upon the amplitude of the electrical signal at a sample whose location is based on the beat fiducial point and the first particular time offset.

In the simplest of terms, the present invention, as claimed in newly-amended independent Claim 14 and new independent Claim 37, is directed to monitor for detecting a cardiac event based on certain features within an electrical signal. Accurate event detection requires accurate measurement of these features, and for features that are heart rate dependent, it is important to adjust for the heart rate. The Applicants have found that the heart rate dependence of the electrogram is patient specific, and as a consequence, heart rate adjustments need to be individually tailored. Put another way, the device of the subject Patent Application takes into account the fact that each individual's heart wave form will exhibit different responses to heart rate changes. For example, the ST segment duration of one person may change one way in response to a heart rate change, while the ST segment duration of another person may change quite drastically in response to that same heart rate change. It is this very concept that the invention of the subject Patent Application takes into account when performing its function. It is not hard to envision this concept in practice when thinking about the differences between the hearts of a top athlete and the heart of an elderly individual. As such, the claimed invention implements the goal

of enabling patient specific adjustment of heart rate dependent measurement parameters, and such a purpose and objective can be found nowhere in the reference cited by the Examiner.

It is respectfully submitted that the Stadler reference neither contemplates nor provides for the purposes and objectives of enabling patient specific adjustment of heart rate dependent measurement parameters. Very simply, the Stadler reference uses a “one size fits all” system that applies the same heart rate adjustment for all patients, and not a system tailored to the needs of individuals as claimed by the subject Patent Application. It is respectfully submitted, therefore, that the Stadler reference nowhere provides for the specific detection of cardiac events wherein the system includes programmability of heart rate dependent measurement parameters.

As such, the Stadler reference does not provide for a system for the detection of cardiac events wherein “the processor is configured to determine the start time of the sub-segment based on the values ... sub-segment timing information” received from an external device which permits heart rate adjustments to be programmed following device implantation of the calculated R-R interval as is required by newly-amended independent Claim 14. Furthermore, the Stadler reference does not provide for a “processor means for determining a first particular offset time relative to a beat fiducial point of one beat of the electrical signal, wherein the first particular offset time is ... based on at least one of the first plurality of user selected offset times” as is required by new independent Claim 37.

Finally, it is respectfully submitted that the remaining Claims are all ultimately dependent upon newly-amended independent Claim 14 and new independent Claim 37, and are believed to show patentable distinction over the reference cited by the Examiner for at least the same reasons as previously presented.

It is now believed that the subject Patent Application has been placed fully in condition for allowance, and such action is respectfully requested.

If there are any additional charges associated with this filing, the Honorable Director for Patents & Trademarks is hereby authorized to charge Deposit Account #18-2011 for such additional charges.

Respectfully submitted,
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